10. 510(K) SUMMARY

NOV 3 0 2012

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

The Assigned 510(k) number is k122419

Submitter: UCP Biosciences, Inc
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Date: August 7, 2012

Contact Person: Dr. Nancy Chen

Trade Name: UCP Home™ Drug Screening Test Cups

Common Name:
Amphetamine Test System
Methamphetamine Test System
Cocaine Test System
Barbiturate Test System
Benzodiazepine Test System
Methamphetamine Test System (MDMA)
Opiates Test System
Methadone Test System
Opiates Test System (Oxycodone)
Amphetamine Test System (Enzyme Immunoassay Phencyclidine)
Cannabinoid Test System
Tricyclic Antidepressant Test System

Product Code: DKZ, DIO, DIS, JXM, DJC, DJR, DJG, LCM, LDJ, LFG

Regulation Section:

CFR 21 § 862.3100
CFR 21 § 862.3150
CFR 21 § 862.3170
CFR 21 § 862.3250
CFR 21 § 862.3610
CFR 21 § 862.3620
CFR 21 § 862.3650

CFR 21 § 862.3870
CFR 21 § 862.3910
Unclassified, Enzyme immunoassay, Phencyclidine

Panel: Toxicology (91)

Device Classification: II

Substantially Equivalent Devices:

UCP Home™ Drug Screening Test Cards/UCP Home™ Drug Screening Test Cups (k091588)

Product Description:

UCP Home Drug Screening Test Cups are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Amphetamine, Barbiturates, Benzodiapines, Cocaines, Marijuana, Methamphetamine, MDMA, Methadone, Opiates, Opiates 300, Oxycodone, Phencyclidine, Tricyclic Antidepressants and their metabolites at the cut-off levels as indicated. The tests can be performed without the use of an instrument.

Intended Use:

UCP Home™ Drug Screening Test Cups:

UCP Home™ Drug Screening Test Cups are rapid, qualitative, competitive binding immunoassays for qualitatively the detection of the following drugs and their metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Marjuana:	Delta-9-THC-COOH	50 ng/mL
Cocaine:	Benzoylecgonine	300 ng/mL
Amphetamine:	D-Amphetamine	1000 ng/mL
Methamphetamine:	D-Methamphetamine	1000 ng/mL
Opiates:	Morphine	2000 ng/mL
Opiate 300:	Morphine	300 ng/mL
Phencyclidine:	Phencyclidine	25 ng/mL
Barbiturares:	Secobarbital	300 ng/mL
Benzodiazepines:	Oxazepam	300 ng/mL
Methadone:	Methadone	300 ng/mL
Oxycodone:	Oxycodone	100 ng/mL
MDMA:	MDMA	500 ng/mL
Tricyclic Antidepressants:	Nortriptyline	1000 ng/mL

The tests are intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide the consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory test in the second step of the two-step process, is provided in the package labeling.

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Oxycodone, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Oxycodone, Tricyclic Antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. The tests provide only preliminary test results, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drug levels.

For Over-The-Counter (OTC) use
For In Vitro Diagnostics only

Comparison to Predicate Devices:

When compared to the predicates, UCP Home Drug Screening Test Cups can qualitatively detect Amphetamine, Barbiturates, Benzodiazepine, Cocaine, Marijuana, Methadone, Methamphetamine, MDMA, Morphine, Opaites 2000, Oxycodone, Phencyclidine, Tricyclic Antidepressant and their metabolites in human urine. Both devices utilize the same cutoff concentrations. Both devices are immunochromatographic, lateral flow assays for the qualitative detection of drugs with visual, qualitative end results. Both tests are intended to provide preliminary analytical test results. Both devices are intended for health care professionals use and for OTC consumers use. UCP Home Drug Screening Test Cups can hold up to three drug tests per strip, whereas the predicates contain one drug test pre strip.

Safety and Effectiveness Data:

Accuracy Studies:

The study design and protocol in the comparison study of using a series of patient specimens is the same as that described in k072062, k091588, k110515. The performance of the candidate devices was compared to the predicate devices in k072062, k091588 and k110515 by using the clinical samples. Total 120 clinical urine samples per one drug test were included in the comparison study. The clinical samples were obtained from the reference laboratories, all clinical urine samples including drug negative urine samples

and drug positive urine samples were tested by the reference method GC/MS, except TCA. The TCA positive urine samples were tested by HPLC method. For each drug test, 10% clinical samples contain drug concentrations between 50% below the cutoff level and the cutoff level, other 10 % clinical urine samples contain drug concentrations between the cutoff level and 50% above the cutoff level. The testing results have demonstrated that 100% agreements between the candidate device and the predicate device, over 97.5% agreement between the candidate devices and the reference method GC/MS in the comparison study by using clinical urine specimens

Consumer Studies

The study design and protocol in the consumer study of UCP Home Drug Screening Test Cup is the same as that described in k091588, k110515, was conducted among 115 lay persons in three geographic regions. Fifty eight females and fifty seven males from ages between 18 and 77 years have participated the study. Fifty eight participants had high school education or less, fifty seven participants had finished college courses. None of the participants had experiences using drug testing products before. The urine samples were prepared to contain strong negative (0% of cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a very weak positive (125% of cutoff), a weak positive (150% of cutoff) and high positive (300% of Cutoff). The urine samples with various drug concentrations were prepared by spiking pure drugs or drug metabolites into drug free human urine, the final drug concentrations in each urine sample were confirmed by GC/MS but TCA, TCA concentrations in the urine samples was confirmed by HPLC. The test results performed by the lay users showed 97% or above agreement rate with GC/MS results and indicate the lay users can perform UCP Home Drug Screening Test Cups satisfactorily by following the test instruction. The post-study survey was conducted to determine if the lay users can understand the test instruction, the meaning of the test results and how to interpret the test results. Consumers were asked 9 questions including whether the test was easy to run, the results was easy to read, how to interpret the test results, importance of confirmatory test and some medicines and foods may affect the test results. Participant responses support that the lay users can understand how to run the test, interpret the test results, the importance of confirmatory test, and some issues concerning certain prescription medicines and foods may affect the test results.

Other Information about Performance Characteristics:

The performance characteristics of UCP Home Drug Screening Test Cups including the precision study, sensitivity study, specificity and cross reactivity study, interference study and stability study have been also established. The results have demonstrated that UCP Home Drug Screening Tests Cup performs satisfactorily when used according to the package inserts.

Conclusion:

The performance data in this submission supports UCP Home™ Drug Screening Test Cups are substantially equivalent to the predicate devices UCP Home™ Drug Screening Test Cards/ UCP Home™ Drug Screening Test Cups (k091588)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 30, 2012

UCP Biosciences, Inc.
c/o Dr. Nancy Chen
1445 Koll Circle, Ste 111
San Jose, CA 95014

Re: k122419
Trade/Device Name: UCP Home Drug Screening Test Cups

Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, DIO, DJC, DJR, DJG, LCM, LDJ, LFG
Dated: November 2, 2012
Received: November 6, 2012

Dear Dr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122419

Device Name: UCP Home Drug Screening Test Cups

Indications for Use:

The UCP Home Drug Screening Test Cups are rapid, qualitative, competitive binding immunoassays for the detection the following drugs and their metabolites in human urine:

Test	Calibrator	Cut-off
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Cocaine	Benzoylecgonine	300 ng/mL
Marijuana	Delta-9-THC-COOH	50 ng/mL
Methadone	Methadone	300 ng/mL
Methamphetamine	D-Methamphetamine	1000 ng/mL
MDMA	MDMA	500 ng/mL
Morphine	Morphine	300 ng/mL
Opiates 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Tricyclic Antidepressant	Nortiptyline	1000 ng/mL

The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The test is intended for over-the-counter (OTC) users as the first step in a two step process to provide consumers, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping the urine specimen to the laboratory, is provided. The test is also intended for health care professional users.

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Oxycodone, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Oxycodone, Tricyclic Antidepressant in urine. The tests provide only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS).

Clinical considerations and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring drug levels.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use X (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Giles

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Office of In Vitro Diagnostics and Radiological Health

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